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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,227	10/20/2003	William Lee		1728

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EXAMINER	
LEITH, PATRICIA A	
ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,227	LEE, WILLIAM	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-4 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-4 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4 are pending in the application.

An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

A listing of registered patent attorneys and agents is available on the USPTO Internet web site http://www.uspto.gov in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450

Claims 1-4 were examined on their merits.

Claim Objections

Claim 1 is objected to because of the following informalities:

Claim 1 recites 'Propylene Glycol, Benzyl Alcohol, and 'Ethyl Alcohol'. These chemicals are conventionally described by using lowercase letters. Correction is necessary.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Inventions targeted for human therapy bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because effective treatments for disease conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence. Claims drawn to

pharmaceutically acceptable compositions and to methods of administering compounds to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments.

In the Instant case, Applicant is claiming an effective amounts of plant extracts in powdered form, wherein the Instant specification demonstrates that it is the extracts of these herbs, which are subsequently powdered, that actually have an effect on treating acne. However, the Specification also teaches that the *starting materials are actually extracts and not the raw plant material*:

"The seven herbal extracts are either in liquid or powder form first weighed and dissolved in distilled water and 60 degrees Celsius thoroughly mixed and allowed to cool..." Applicant did not disclose how the plants were initially extracted. It is *a priori* unpredictable to determine what herbal extracts Applicant started with. Because it is not possible to determine what powdered/liquid extracts Applicant started with, the skilled artisan would not be able to make or use the topical solution of the Instant claims.

It is well known in the herbal arts that plant extraction as well as pharmacological activities of plant extracts is highly unpredictable. It is well known in the herbal art that polarity of solvents plays a key role in determining the final product obtained by an extraction. However, because many phytochemicals remain undiscovered, the skilled artisan has to make his best educated guess as to what types of phytochemicals will be

successfully extracted with a solvent of a particular polarity. Often times, unless the constituents in a particular plant extract have been well evaluated and documented in the literature, the skilled artisan must adhere to trial and error protocols in order to quantitatively determine phytochemical constituents present in samples obtained from respective extraction procedures. These procedures are common when, for example, a plant or part thereof has been documented in the literature as possessing some medicinal quality. The skilled artisan will carry out numerous tedious extraction protocols in attempt to isolate the particular ingredient(s) which has/have this medicinal quality. Typically, beginning with the first crude extraction, ***it is a guess*** as to weather or not the extract will possess the inherent medicinal quality. Take for example, the grape, *Vitis vinefera*. If this fruit was documented in the literature as having a particular medicinal quality, the skilled artisan may feel the need to extract and isolate the medicinally beneficial ingredient(s)therefrom.

The skilled artisan will, by trial and error, attempt to perform step-wise extractions to uncover the active extract. If the first extraction attempt with a particular solvent fails, another solvent will be tried. Thus, beginning with the initial extraction, a first product is yielded which was extracted with the solvent, and a second product is yielded which remains because it did not possess a similar polarity to the solvent. Each successive extraction yields different products due to the exclusion of ingredients based on the polarity of the solvents solvating constituents with similar polarities. Subsequently, *the properties of each respective product (extract) would need to be*

evaluated for efficacy.

Additionally, according to the Stedman's dictionary 27th Ed, the term 'extract' means 'A concentrated preparation of a drug obtained by removing the active constituents of the drug with suitable solvents...'. Thus, purification of any product obtained via an extraction to yield a specific phytochemical would constitute an 'extract' judging from the definition provided by Stedman's Medical Dictionary. Therefore, resveratrol, a phytochemical inherent in grapes, is deemed to be an 'extract' of grapes since it is obtained by the process outlined in Stedman's. Therefore, each respective phytochemical found within grapes constitutes an extract once it is 'extracted' away from the rest of the grape's constituents. Here, the unpredictability with regard to the term 'extract' in the claims has grown exponentially.

Hence, ***each product obtained from a plant extraction is unpredictable in nature***. Even the most skilled of artisans would need to quantify each product for constituents as well as medicinal efficacy. Unpredictability with regard to plant extracts has been well documented in the art. Revilla et al. for example (1998) showed that the slightest variations in polarity of solvent and reaction time upon grape extraction provided respective products with unique characteristic properties (See Tables 1, 2, 4, 5, 6 and 7). In turn, each product would possess varying pharmacological properties based upon their respective phytochemical constituents.

Applicants have not provided any information with regard to how to make the starting material comprising extracts of the seven herbs as listed in Claim 1 and p. 2 of the Instant specification. Thus, to practice the instant invention *s* would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner to ascertain what starting materials Applicant actually used. This inventive contribution would involve tedious trial and error protocols without the expectation of success for the reasons set forth *supra.*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 provide for more than one sentence. It cannot be ascertained in each instance, if the language cited after the period is part of the claimed invention. Claims should be presented in one sentence in order to properly convey that all of the language listed in the claim is part of the claimed invention.

Claim 1 recites 'the hair follicle and sebaceous gland'. 'the hair follicle' and 'sebaceous gland' lack antecedent basis in the claim. Claim 1 recites 'the black head of the comedones'. Both of 'the black head' and 'the comedones' lack antecedent basis in the claim. Claim 1 further recites 'the herbal extract' and 'the transdermal system' which both lack antecedent basis.

Claim 1 recites percentages, however, it is unclear if these are percentages of the plant powders as compared to each other, or in the composition; clarification is necessary. Further, the claim states 'ethyl alcohol 70% approx. 1-20%. This phrase is confusing in that it appears that more than one percentage is being claimed. In order to clarify this statement, it is suggested that the claim be reworded to read: 'approximately 1.0 – 20.0% of 70% ethyl alcohol'.

Claim 3 recites 'the area' which lacks antecedent basis in the claim. Further, claim 3 recites 'A method for treating a patient having acne lesions'. This phrase is ambiguous in that it does not clearly state what disease the method is treating. For further clarification in order to overcome this rejection, a suggestion for rewording the phrase is: 'A method for treating acne lesions in a patient in need thereof'.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is

an omnibus type claim. Applicant is asked to distinctly claim a particular method for making a topical solution; i.e., include method steps.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9/1/05

Patricia Leith
Primary Examiner
Art Unit 1655